K090624

APR - 2 2009

510(k) SUMMARY

Submitted By: Susanne Galin, RAC
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2296
February 20, 2009

Device:

Trade Name:	Cook MReye Embolization Coils
Proposed Classification Name:	Vascular embolization device 21 CFR §870.3300, Product Code KRD
Indications for Use:	The Cook MReye Embolization Coil is used for peripheral arterial and venous vessel embolization procedures.
Predicate Devices:	Cook MReye Embolization Coils (K052834) Cook Stainless Steel Embolization Coils (Pre-amendment)

Device Description:

The Cook MReye Embolization Coil is a device used for peripheral arterial and venous vessel embolization procedures. The coil is pre-loaded into a cartridge to facilitate delivery into a microcatheter, which then delivers the coil to the embolization site.

Substantial Equivalence:

The identical indications for use, technological characteristics, and similar dimensions of the Cook MReye Embolization Coils as compared to the predicate device supports a determination of substantial equivalence.

Test Data:

The following testing data were presented to demonstrate that the Cook MReye Embolization Coils meet applicable design and performance requirements:

- Coil deformation testing
- Delivery friction testing
- Embolization fiber pull-out testing
- Cannula to catheter delivery testing

The results of these tests provide reasonable assurance that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Incorporated, Inc.
c/o Ms. Susanne Galin, RAC
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

APR - 2 2009

Re: K090624
Cook MReye® Embolization Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: March 6, 2009
Received: March 9, 2009

Dear Mr. Galin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090624

Device Name: Cook MReye® Embolization Coil

Indications for Use: The Cook MReye Embolization Coil is used for peripheral arterial and venous vessel embolization procedures.

Prescription Use XX OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K090624